

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

ROLF HAZLEHURST,

Plaintiff,

v.

Civil No. _____

CENTERS FOR DISEASE CONTROL,

Defendant.

COMPLAINT

(For review of agency action, declaratory and injunctive relief under the Administrative Procedure Act to compel the testimony of CDC employee Dr. William Thompson in a state medical malpractice action; and request for expedited treatment)

1. Plaintiff Rolf Hazlehurst brings this action for declaratory and injunctive relief to reverse the denial by the Centers for Disease Control (CDC) of his request for the testimony of a CDC employee, Dr. William Thompson, in a medical malpractice action pending in Tennessee state court. The actions seek damages for injuries to his minor child, Yates, from vaccines administered at The Jackson Clinic on February 8, 2001, in violation of the duty of informed consent and of appropriate standards of medical care. A central issue in the cases is whether vaccines can cause autism, at least in rare cases such as Yates, who also suffers from mitochondrial dysfunction, and whether experts can offer admissible opinions as to such causation. Dr. Thompson was a co-author of a 2004 study that supposedly exonerated the MMR vaccine of autism causation. He came forward as a whistleblower in August, 2014, claiming that he and his colleagues in the CDC Vaccine Safety Branch were ordered to commit scientific fraud, destroy evidence and manipulate data to conceal the link between autism and vaccines.

Dr. Thompson revealed that despite the CDC's claims to the contrary, the vaccine safety studies in question demonstrated a causal link between vaccines and autism symptoms. His testimony is thus essential to success in the state cases.

JURISDICTION AND VENUE

2. This Court has jurisdiction under 28 U.S.C. § 1331 (federal question) and § 1361 (compel performance of duty). The requested relief is authorized by the Administrative Procedure Act, 5 USC § 706(1) (compelling agency action wrongfully withheld), (2)(A) (setting aside agency action that is arbitrary capricious or contrary to law). Venue is proper under 28 USC § 1391(e)(1) because this is an action against the CDC, an agency of the United States and Plaintiff resides in this judicial district.

FACTUAL BACKGROUND

3. Plaintiff's son Yates was born on February 11, 2000. He was developing normally until he experienced a severe adverse reaction (illness, screaming, shaking) to his "routine" six-month vaccines. Although this should have been a contraindication to any further vaccination, the Clinic administered four (4) additional vaccines on February 8, 2001, even though the reason for the visit to the clinic was a serious acute ear infection. Further, contrary to federal law, the clinic failed to provide Yates' parents with the Vaccine Information Statements (VIS) required by the Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-26(d). These warned parents to delay or avoid vaccines if the child was moderately ill with, *e.g.*, otitis media (ear infection). Plaintiff and a reasonable person similarly situated would have refused the vaccines had they been provided with the VIS forms and adequate informed consent. Twelve (12) days later Yates developed a high fever, vomiting and rash, and regressed quickly into

autism. Yates experienced significant regression in his development after his childhood vaccines, and has been diagnosed with Autism Spectrum Disorder.

4. Plaintiff (along with his wife and injured son) filed medical malpractice actions against the clinic and doctor. *Rolf Hazlehurst and Angela Hazlehurst v. The Jackson Clinic and E. Carlton Hayes, M.D.*, Madison County Circuit Court Docket No. C-04-149 (subsequently non-suited); *William Yates Hazlehurst (a minor child) v. The Jackson Clinic and E. Carlton Hayes, M.D.*, Madison County Circuit Court Docket No. C-10-290 (Malpractice Action). This action seeks damages for injuries sustained by Yates as a result of the vaccinations administered at The Jackson Clinic (which included MMR), and are based upon failure of informed consent, failure to provide the required VIS forms, and the negligent administration of vaccines which were contraindicated due to Yates' medical condition.

5. Defendants in the Malpractice Action seek summary judgment based upon, in part, allegations that there is no proven causal link between vaccines and autism. They also seek to exclude Plaintiff's causation experts because any opinion that vaccines can cause autism, or did cause autism even in the rare case of Yates, is unreliable due to the fact that their opinions are not generally accepted in the medical community. Defendants' argument rests, in large part, on medical studies from the CDC's website, including a study authored by and later drawn into doubt by Dr. Thompson.

6. Defendants also rely on the opinion of the CDC that "vaccines do not cause autism."¹ As for studies, the only epidemiological study of MMR-autism causation in US children on which Defendants rely was conducted by the CDC. DeStefano F, Bhasin TK, Thompson WW, Yeargin-Allsopp M, Boyle C, *Age at First Measles-Mumps-Rubella*

¹ <https://www.cdc.gov/vaccinesafety/concerns/autism.html> (visited February 3, 2017).

Vaccination in Children With Autism and School-Matched Control Subjects: A Population-Based Study in Metropolitan Atlanta. 2004;113:259-266 (DeStefano Study).

7. Defendants rely on the DeStefano Study and on a supposed lack of studies showing a causal association to claim that the opinion testimony of Hazlehurst's causation experts is purely speculative and therefore unreliable and inadmissible under Tennessee law. For example, Defendants assert that the opinions of Dr. Corbier, one of the Plaintiffs' causation experts, "are not based upon any reliable scientific studies and are contrary to the scientific community and research. ... Extensive research has been repeatedly reviewed and summarized by medical organizations, including the Centers for Disease Control (CDC) and American Academy of Pediatrics (AAP), which shows that Dr. Corbier's causation claims are scientifically invalid." Defendants' Motion to Exclude Causation Opinions of Jean-Ronel Corbier, M.D., and for Summary Judgment (Dec. 4, 2015) pp. 21-23.

8. Defendants further claim in their December 15, 2016 motion to exclude testimony from Hazlehurst's causation experts:

The opinions [of Plaintiffs' experts] are not based upon any reliable, scientific studies and are admittedly contrary to the scientific community and the vast amount of research that exists today. . . . [T]he causation testimony of [Hazlehurst's experts] is based upon studies they hope will be done in the future and that they hope will show a causal link. However, as of now (over 15 years after the alleged malpractice), all of the completed studies and research still show no causal link. . . . [A]ll of the reliable and authoritative medical organizations that have studied the topic have concluded that vaccines do not cause autism, which demonstrates the unreliability of the causation opinion at issue. . . . In sum, Plaintiffs have not introduced evidence which affords a reliable scientific basis for the conclusion that it is more likely than not that the conduct of the Defendants was the cause in fact of the result. . . . The causation opinions lack a sufficient basis of scientific reliability and trustworthiness. . . . Dr. Zimmerman testified that a link between vaccines and autism has not yet been shown and that at this time there is merely a "possible association." . . . [A]ccording to Plaintiffs' own expert, there merely exists today a possibility of a causal link between vaccines and autism that may be understood sometime in the future. . . . [The experts']

causation hypothesis is considered a “MYTH” and has been refuted by countless authoritative organizations and studies.

Id. at pp. 5, 12, 18, 32, 33, 34, 43.

9. Malpractice Defendants’ causation expert has stated, for example:

[Dr. Corbier’s] causation opinions regarding a relationship between vaccines and Yates Hazlehurst’s medical condition are completely speculative and not based upon medical science. I have followed the issues of vaccines and autism and related conditions for many years, and have followed the extensive medical literature on the subject. The scientific consensus is clear – vaccines do NOT cause autism or mitochondrial disorders. The extensive literature has been reviewed by expert groups and summarized repeatedly by organizations including [CDC]. . . . [T]here is NO evidence that vaccines trigger autism in any children and strong evidence that they DO NOT. . . . Simply put, Dr. Corbier’s causation theories in this case have no scientific basis – in fact they have been repeatedly and emphatically discredited by extensive scientific literature.

December 2, 2015 Affidavit of Dr. B. Keith English at ¶¶ 2, 5, 6.

10. Exhibit B to Dr. English’s affidavit is a CDC webpage² listing as a “featured resource” Vaccines and Autism: A Summary of CDC Conducted or Sponsored Studies.³ The DeStefano Study is the only study of the MMR-autism link in US children.

11. The DeStefano Study has thus become a central issue in the Malpractice Action. It has been used by the CDC to persuade the Institute of Medicine (IOM) Immunization Safety Review Committee to find in its 2004 report that the epidemiologic evidence favored rejection of the hypothesis that vaccines caused autism at the population level, although IOM left open the possibility that vaccines could cause autism in a genetically susceptible subset of children like Yates. The Department of Justice used the DeStefano Study and the IOM report to persuade the Court of Federal Claims (Vaccine Court) to find that vaccines did not cause Yates’ autism.

² The version of the page cited by Dr. English is headed “Vaccines Do Not Cause Autism,” and has a section titled “there is no link between vaccines and autism.” However, the current page includes a list of MMR studies supposedly exonerating MMR of causing autism but does not list the DeStefano study, and no longer links to the DeStefano study, possibly because of the ongoing investigation of scientific fraud in connection with that study. See <https://www.cdc.gov/vaccinesafety/concerns/autism.html> (visited 2/1/17).

³ [file:///C:/Users/Jim/Downloads/cdc_27788_DS1%20\(1\).pdf](file:///C:/Users/Jim/Downloads/cdc_27788_DS1%20(1).pdf) (visited 2/1/17).

Hazlehurst v. HHS, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *affirmed*, 88 Fed. Cl. 473 (2009), *affirmed*, 604 F.3d 1343 (Fed. Cir. 2010). This was one of the six (6) test cases that eventually guided the dismissal of approximately 5,000 additional cases alleging vaccine-cause autism. The fraud and research misconduct revealed by Dr. Thompson were thus instrumental in depriving not only Plaintiff Hazlehurst of his day in Vaccine Court, but also thousands of other vaccine-injured children with autism.

12. In August, 2014, a senior scientist at the CDC, Dr. William Thompson, came forward as a whistleblower to report scientific fraud in the DeStefano Study of MMR and autism which he co-authored in 2004. *Age at First Measles-Mumps-Rubella Vaccination in Children With Autism and School-Matched Control Subjects: A Population-Based Study in Metropolitan Atlanta*. *Pediatrics*, 113:259-266 (2004).

13. Dr. Thompson released a statement on August 27, 2014, admitting:

I regret my co-authors and I omitted statistically significant information in our 2004 article published in the journal *Pediatrics*. The omitted data suggested that African-American males who received the MMR [measles, mumps, rubella] vaccine before 36 months were at increased risk for autism. Decisions were made regarding which findings to report after the data was collected, and I believe that the final study protocol was not followed.

My concern has been the decision to omit relevant findings in a particular study for a particular sub-group for a particular vaccine. There have always been recognized risks for vaccination and I believe it is the responsibility of the CDC to properly convey the risks associated with receipt of those vaccines.

August 27, 2014 Statement of William W. Thompson, Ph.D., Regarding the 2004 Article Examining the Possibility of a Relationship Between MMR Vaccine and Autism.⁴

14. Dr. Thompson filed a “whistleblower document” with Congress on September 9, 2014. He stated in part:

⁴ <https://morganverkamp.com/statement-of-william-w-thompson-ph-d-regarding-the-2004-article-examining-the-possibility-of-a-relationship-between-mmr-vaccine-and-autism/> (visited 2/1/17).

I believe we intentionally withheld controversial findings from the final draft of the DeStefano et al (2004) Pediatrics paper. We failed to follow the final approved study protocol and we ran detailed in depth RACE analyses from October 2001 through August 2002 attempting to understand why we were finding large vaccine effects for blacks. The fact that we found a strong statistically significant finding among black males does not mean that there was a true association between the MMR vaccine and autism-like features in this subpopulation. This result would probably have led to designing additional better studies if we had been willing to report the findings in the study and manuscript at the time that we found them. The significant effect of early vaccination with the MMR vaccine might have also been a proxy for the receipt of thimerosal vaccines early in life but we didn't have the appropriate data to be able to code the level of thimerosal exposure from the MADDSP school records.

In addition to significant effects for black males, we also found significant effects for "isolated autism cases" and for the threshold of 24 months of age. If we had reported the 24 month effects, our justification for ignoring the 36 month significant effects would not have been supported. In the discussion section of the final published manuscript, we took the position that service seeking was the reason we found a statistically significant effect at 36 months. This was a post-hoc hypothesis regarding the findings after we confirmed one of our primary hypotheses. Because we knew that the threshold for 24 months was also statistically significant, reporting it would have undermined the hypothesis that service seeking was the reason we found an effect at 36 months.

See 161 Cong. Rec. H5602 (July 29, 2015).

15. The Malpractice Defendants argue they should be granted summary judgment because there were no studies finding that vaccines in general or MMR in particular cause autism, relying to a large extent on the DeStefano Study and its progeny. Upon information and belief, and based upon public statements made by him, Dr. Thompson possesses information that refutes one of the Malpractice Defendants' main contentions, *i.e.* that no studies have found that vaccines in general or MMR in particular cause autism.

16. In the alternative, the Malpractice Defendants argued that Hazlehurst's causation experts should be barred from testifying because their opinion testimony that the vaccines Yates received on February 8, 2001, were more likely than not the cause of his autism. Upon information and belief, and based upon public statements made by him, Dr. Thompson possesses

information that supports the testimony of Plaintiffs' causation experts and establishes a link between autism and vaccines in general and/or MMR in particular.

17. Plaintiff Hazlehurst argues that the findings from the DeStefano Study that were concealed show that there is a causal association between MMR and the type of autism suffered by Yates, that the CDC knew that MMR could cause autism, and this finding was withheld from the IOM's Vaccine Safety Review Committee.

18. Accordingly, Hazlehurst sought the testimony of Dr. Thompson by filing a request on September 9, 2016, pursuant to agency regulations, 45 C.F.R. § 2.4, issued to facilitate such requests following the decision of the Supreme Court in *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951). **Exhibit 1.**

19. Hazlehurst's request satisfied the elements required by the regulations: (1) stating the nature and reasons for the testimony of Dr. Thompson; (2) demonstrating the Dr. Thompson's testimony relating to the fraud and true findings in the DeStefano Study was not reasonably available by other means; and (3) demonstrating that Dr. Thompson's testimony was in the public interest. 45 C.F.R. § 2.4(a).

20. The CDC summarily denied Hazlehurst's *Touhy* request on September 22, 2016, claiming that "the testimony you seek is available by other means" and that Dr. Thompson's "testimony would not substantially promote the objectives of the CDC or HHS." **Exhibit 2.**

21. The CDC's denial went on to state that the three (3) studies covered by the request were published in 2004, 2007 and 2011, after Yates' vaccinations in 2000 and 2001, and asserted that "these studies are not relevant to establishing the standard of care that existed at the time of vaccinations."

22. The CDC went on to claim incorrectly that “your current private litigation is not the proper forum to address” concerns about the validity of the studies, and “CDC still considers these studies to be valid and to provide further evidence, along with a large body of other scientific studies, that vaccines do not cause autism.” The CDC did concede, however, that it is reviewing allegations of research misconduct with respect to the DeStefano Study.

23. The CDC next claimed that the underlying data from the studies was publicly available for “analysis by others.”

24. The CDC next argued that “the objective of ensuring the integrity of its scientific work and resulting publications is better addressed through normal scientific and other processes and is not served by providing testimony in an individual case.”

25. Finally, the CDC interposes the “floodgate” argument, that it simply cannot grant all such requests for testimony in private litigation.

COUNT ONE – ADMINISTRATIVE PROCEDURE ACT

26. The CDC’s decision to block the testimony of Dr. Thompson was arbitrary, capricious, and an abuse of discretion under 5 U.S.C. § 706, and should be held unlawful and set aside, and his testimony in the Malpractice Action should be compelled.

27. Contrary to the CDC’s claim, Dr. Thompson’s testimony relates to whether or not the vaccines, particularly MMR, were the cause of his injuries that followed from the improper administration of the vaccines in violation of the standard of care, and not to the standard of care applicable to administration of the vaccines to Yates in 2000 and 2001. Dr. Thompson’s testimony is thus essential and irreplaceable to ensure that Yates receives a fair trial in the Malpractice Action.

28. The CDC's claim that "vaccines do not cause autism," at least in rare cases, is contradicted for example:

- a. by Dr. Thompson's statements relating to a causal association particularly between MMR and "isolated" autism (suffered by Yates) that was concealed from the DeStefano Study on which he worked;
- b. by autism cases from Vaccine Court dating back to 1990 in which the government has paid several hundred million dollars in injury compensation;
- c. by official statements to the press that the government has compensated "cases in which children exhibited an encephalopathy, or general brain disease . . . [which] may be accompanied by a medical progression of an array of symptoms including autistic behavior, autism, or seizures;" and
- d. by an explanation by then CDC director Julie Gerberding in March, 2008, that a reaction to vaccines in a child (Hannah Poling) recently compensated [in a case virtually identical to Yates] with an underlying mitochondrial dysfunction can cause autism. Plaintiff's experts in the Malpractice Action include Dr. Zimmerman and Dr. Kelly, testifying that Yates and Hannah are virtually identical cases, and who both served as CDC experts in the Poling case arguing in favor of compensation.

29. The public availability of datasets does not diminish the need for Dr. Thompson's testimony because Defendants in the Malpractice Action are also relying on the CDC to exonerate vaccines from causing autism, and Dr. Thompson's testimony, as a whistleblower, is the only way to learn what the CDC "knew" and when did it know it. The CDC is not claiming that the data and findings that were withheld from the public in the DeStefano Study are now being made public. Dr. Thompson's testimony is thus the only way to document what the CDC "knew" in 2004, and why and how this information was concealed from the public, the IOM, and the Vaccine Court proceedings (in which Plaintiff Hazlehurst was involved).

30. It serves, rather than harms, the public interest to have external "sunlight" expose whatever research fraud occurred at the CDC with respect to covering up a causal association between vaccines and autism, even in rare cases. A purely internal review process, as suggested

by the CDC, is inherently unreliable because organizations accused of wrongdoing are not normally trusted to investigate themselves. Furthermore, an internal review does nothing to ensure that Yates receives a fair trial in the Malpractice Action.

31. Moreover, the benefit to Yates from winning his case far outweighs keeping the CDC's internal investigation. Congress mandated that all children suffering vaccine injury receive generous compensation in the Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-11, *et seq.*, including reliance on private litigation. In particular, Congress mandated that all parents receiving vaccines for their children receive informed consent including a Vaccine Information Statement, *Id.* § 300aa-26. The failure to provide the required VIS forms is a central issue in the Malpractice Action.

32. Finally, the CDC's "floodgate" argument lacks merit because this is a one-off case, and once Dr. Thompson's testimony is obtained via deposition it can be made available if any other need arises. His testimony relates to general causation, to the honesty of the CDC claims, and the reliability of scientific studies, and is not so fact-specific with respect to the Malpractice Action that it might encourage repetitive requests.

PRAYER FOR RELIEF

Wherefore, Plaintiff requests that the Court:

- a. Expedite the processing of this case;
- b. Declare that Plaintiff can obtain the testimony of CDC employee Dr. William Thompson for use in the Malpractice Action;
- c. Enjoin CDC from preventing the testimony of Dr. William Thompson; and
- d. Provide Plaintiff with such additional relief as is just and the Court deems appropriate, including an award of attorney fees and costs.

Respectfully submitted,

s/ W. Bryan Smith

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